

## **REMARKS**

### **Introduction**

Claims 1 and 9 have been amended to re-introduce material that was included in the response filed December 12, 2007, but was inadvertently omitted from the listing of claims filed June 20, 2008. Applicant also notes that Claims 2 and 10 were cancelled in the reply filed December 12, 2007, since the subject matter of those claims were incorporated into the respective independent claims, Claims 1 and 9. Therefore, the currently pending claims are Claims 1, 3, 9 and 11.

Applicant also requests that the status of Claims 5 and 7 be changed to withdrawn instead of cancelled. Applicant submits these claims are method claims that have been amended to include all the limitations of the product claim, Claim 1. For the reasons discussed below, Applicant submits that Claim 1 is patentable and accordingly requests that Claims 5 and 7 be rejoined.

### **Claim Rejections 35 U.S.C. § 112**

The Examiner has rejected Claims 1 and 9 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states “[i]t is unclear how the occlusive member can be located distally of the distal opening, yet be in contact with the lumen that is defined as extending between and connect the distal and proximal openings.” The Examiner further states that the phrase “such that blood flow through said proximal opening” is vague and unclear.

With respect to the Examiner’s first contention, Applicant respectfully submits that spatial relationship of the occlusion member, distal opening and lumen is not inconsistent or unclear. Specifically, the lumen extends distally of the “distal opening.” This is shown in Fig. 8, for example. The term “distal opening” provides a relative indication of its location with respect to the proximal opening, but is not intended to indicate the limit of the lumen. This is also consistent with the description that the lumen extends between the proximal and distal openings. As described above, the lumen also extends to a position distal of the distal opening, allowing

the occlusion member to be in contact with the lumen and be distal of the distal opening. Therefore, Applicant respectfully submits that the claims as written are sufficiently clear.

With respect to the phrase “such that blood flow through said proximal opening,” Applicant has amended Claims 1 and 9 to clarify that when the distal opening is located within the lumen of the blood vessel, blood enters the distal opening, flows through the lumen and exits through the proximal opening, which is visible outside the patient’s body. As described in the specification, this “bleed back” lumen allows the operator to accurately determine when the occlusion member is positioned within the blood vessel and subsequently when the occlusion member has been withdrawn to a position just outside the blood vessel lumen.

For these reasons, Applicant respectfully requests that the Examiner withdraw the §112 rejection of Claims 1 and 9.

#### **Claim Rejections 35 U.S.C. § 102**

Next, the Examiner has rejected pending Claims 1, 3, 9 and 11 under 35 USC §102(b) as being anticipated by Diaz (USPN 5,690,674). The Examiner contends that Diaz discloses all the limitations of the claims, including an elongate member that is “adapted to extend into a blood vessel of a patient such that blood flow through the proximal opening is visible outside of the patient’s body (for example, see Figure 1).” Applicant respectfully disagrees with this interpretation of the Diaz reference.

First, although the Examiner references Figure 1, Applicant has carefully reviewed the specification and figures and believes that the Examiner meant to specify a different figure. Figure 1 of the Diaz reference shows only a cross-sectional view of a closure plug, and provides no teaching regarding a proximal opening through which blood flow would be visible outside the patient’s body. The only figure that appears to be relevant is Fig. 5, which does show distal opening 302 positioned within a blood vessel lumen, such that blood flow through lumen 310 would be visible through proximal opening 301. Accordingly, Applicant assumes the Examiner meant to refer to Fig. 5.

However, Diaz still fails to disclose a device having the claimed features, nor can the device disclosed by Diaz achieve the claimed functionality. Specifically, Diaz has no structure

that can function as a bleed back lumen to show the current position of an occlusion member relative to the blood vessel. As required by the independent Claims 1 and 9, the elongated member must have an occlusion member located distal to the distal opening and when the distal opening is located in the blood vessel lumen, blood can enter the distal opening, travel through the lumen and exit through the proximal opening.

In contrast, the device disclosed by Diaz does not show an occlusion member located distal to the distal opening such that when the distal opening is located in the blood vessel, blood can flow through the lumen and be seen exiting the proximal opening. As discussed above, the only figure in Diaz showing a configuration that would allow blood to enter the distal opening 302 and exit the proximal opening 301 is Fig. 5 which does not include an occlusion member. As soon as an occlusion member 100 is included in the Diaz device, it prevents flow through lumen 310, so that blood cannot flow through lumen 310. For example, Figs. 6-9 clearly show that the occlusion member 100 is either not distal to distal opening 302 or it seals distal opening 302, preventing the bleed back function. Furthermore, the Diaz device cannot function as required by the claims, because the stop 230 prevents a user from pushing the occlusion member 100 far enough out of the device to unseal distal opening 302. The only time Diaz discloses an occlusion member 100 that is indeed distal of distal opening 302 is when occlusion member 100 has been detached and device 300 has been withdrawn, so that distal opening 302 is no longer positioned within the blood vessel. Clearly, this configuration does not allow blood flow through lumen 310 that would be visible through proximal opening 301.

For the above reasons, Applicant respectfully submits that Diaz fails to disclose the features required by Claims 1 and 9. Namely, Diaz does not disclose an elongated member wherein the occlusion member is located distal to the distal opening and wherein the distal opening positioned within a blood vessel permits blood to flow through the lumen and exit the proximal opening where it is visible outside the patient's body. Since Claims 3 and 11 depend from Claims 1 and 9, respectively, Applicant submits that Diaz fails to anticipate them for the reasons discussed above. Accordingly, Applicant respectfully requests that the Examiner withdraw the § 102 rejection of pending Claims 1, 3, 9 and 11 over Diaz. Also, as discussed above, Applicant requests that method Claims 5 and 7 be rejoined.

Application No. 10/687,848  
Amendment dated December 5, 2008  
Reply to Office Action dated September 8, 2008


**Conclusion**

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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Date: December 5, 2008

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